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PRVD2007-15

Proposed Re-evaluation Decision

PYRAZON

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Proposed Re-evaluation Decision

After a re-evaluation of the herbicide pyrazon, under the authority of the Pest Control Products Act, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing continued registration of pyrazon products for sale and use in Canada.

An evaluation of available scientific information found that pyrazon products do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of pyrazon uses, new risk reduction measures must be included on the labels of all products. No additional data are being requested at this time.

The PMRA's pesticide re-evaluation program considers the potential risks and the value of pesticide products, to ensure they meet modern standards established to protect human health and the environment.

This proposal affects all end-use products containing pyrazon registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision (PRVD) is a consultation document¹ that summarizes the science evaluations for pyrazon and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides the technical information on the assessment of pyrazon.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

¹ "Consultation statement" as required by subsection 28 (2) - *Pest Control Products Act* 2002 (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

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Overview

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA is re-evaluating active ingredients and their uses to determine their continuing acceptability in relation to human health, environment and value. Pyrazon is one of the active ingredients to be re-evaluated during the current re-evaluation cycle. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Pyrazon has been re-evaluated under the Re-evaluation Program 1, which relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate risk reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account Canadian use patterns and issues (e.g. the Federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products is also conducted.

The USEPA conducted a re-evaluation of pyrazon and published its conclusions in a 2005 RED. On the basis of health and environmental risk assessments, the USEPA concluded that pyrazon was eligible for reregistration with the implementation of risk reduction measures. Based on the comparison of U.S. and Canadian use patterns, the USEPA assessments described in this RED document were considered an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Pyrazon?

Pyrazon is a herbicide used to control annual broadleaved weeds in sugar beets and red table beets. Pyrazon is applied by farm workers and professional applicators using ground equipment.

Health Considerations

Can Approved Uses of Pyrazon Affect Human Health?

Additional risk reduction measures are required on pyrazon labels. Pyrazon is unlikely to affect your health when used according to revised label directions.

Exposure to pyrazon may occur through diet (food and water), working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that pyrazon was unlikely to affect human health provided that risk reduction measures were implemented. These conclusions were considered applicable to the Canadian situation and equivalent risk reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Pyrazon is currently registered in Canada for use on red table beets and sugar beets. As noted, pyrazon may be used on other crops in other countries which are imported into Canada. There are no specific Canadian MRLs established for pyrazon. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

Environmental Considerations

What Happens When Pyrazon Is Introduced Into the Environment?

Additional risk reduction measures are required on pyrazon labels. Pyrazon is unlikely to affect non-target organisms when used according to revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to pyrazon in the environment. Environmental risk is assessed by the risk quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration (EEC) to the relevant effects endpoint of concern. The resulting RQs are compared to corresponding levels of concern (LOCs). An RQ less than the LOC is considered as a negligible risk to non-target organisms, whereas, an RQ greater than the LOC indicates some degree of risk.

The USEPA concluded that the reregistration of pyrazon was acceptable provided risk reduction measures to further protect the environment were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk reduction measures are required.

Measures to Minimize Risk

Registered pesticide product labels contain specific directions for use which include risk reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of pyrazon, further risk reduction measures are proposed in addition to those already identified on existing pyrazon product labels. These additional measures are designed to further protect human health and the environment, and are summarized as follows:

Human Health

- To protect workers re-entering treated sites: a restricted-entry interval

Environment

- To reduce potential surface and groundwater contamination: additional advisory label statements
- To protect non-target sensitive aquatic and terrestrial plants: buffer zones

Next Steps

Before making a final re-evaluation decision on pyrazon, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a *Re-evaluation Decision*² document which will include the decision, the reasons for it, a summary of comments received on the proposed decision, and the PMRA's response to these comments.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act* (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

Science Evaluation

1.0 Introduction

Pyrazon is a herbicide, which acts by inhibiting photosynthesis in green plants.

Following the re-evaluation announcement for pyrazon, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of end-use products in Canada.

The PMRA used recent assessments of pyrazon from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for pyrazon, dated September 2005, as well as other information on the regulatory status of pyrazon in the United States, can be found on the USEPA's website at www.regulations.gov/fdmspublic/component/main.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common Name: Pyrazon

Function: Herbicide

Chemical Family: Pyridazinone

Chemical Name

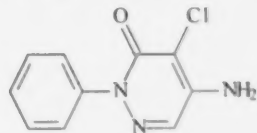
1 **International Union of Pure and Applied Chemistry (IUPAC):** 5-amino-4-chloro-2-phenylpyridazin-3(2H)-one

2 **Chemical Abstracts Service (CAS):** 5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone

CAS Registry Number: 1698-60-8

Molecular Formula: C₁₀H₈ClN₃O

Structural Formula:



Molecular Weight: 221.6 amu

Purity of the Technical Grade Active Ingredient (TGAI):	65.0% nominal (lower limit: 63.05; upper limit: 66.95%)
Registration Number:	21115

Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	<0.01 mPa at 20°C
Henry's law constant	<6.52 × 10 ⁻⁶ Pa · m ³ /mol (calculated) 5.5 × 10 ⁻¹¹ atm · m ³ /mol at pH 7
Ultraviolet (UV)/ visible spectrum	not expected to absorb UV at λ >300 nm
Solubility in water at 25°C	4000 mg/L (0.34 g/L) at pH 7
<i>n</i> -Octanol–water partition coefficient	Log <i>K</i> _{ow} = 1.19 at pH = 7
Dissociation constant (pKa)	pKa = 3.38

2.3 Comparison of Use patterns in Canada and the United States

Pyrazon is a herbicide registered in Canada for the control of a variety of weeds. It acts by inhibiting photosynthesis in green plants. It is used on sugar beet and red table beet crops. Pyrazon is applied at fall preplant (Western Canada only), spring preplant, pre-emergent to weeds, or early post-emergent to weeds. It is applied once per growing season at up to 4.4 kg a.i./ha. The end-use products are formulated as a suspension and as a wettable granule, and are applied by groundboom using broadcast or band application.

A comparison of U.S. and Canadian use patterns was conducted. The Canadian formulation type of end-use products and use sites are among those registered in the U.S. The maximum Canadian application rate is lower than those registered in the U.S. (8.52 kg a.i./ha, up to twice per year). The Canadian potential application methods are among those registered in the U.S. of groundboom broadcast or band, low-pressure handwand, and backpack sprayer. Based on this comparison of use patterns, it was concluded that the USEPA RED for pyrazon is an adequate basis for the re-evaluation of the Canadian uses of pyrazon.

All current uses are being supported by the registrant and were therefore considered in the re-evaluation of pyrazon. Appendix I lists all pyrazon products that are registered under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

The USEPA conducted a re-evaluation of pyrazon and published their conclusions in a 2005 RED. In this document, the USEPA concluded that the end-use products formulated with pyrazon met the safety standard under the U.S. *Food Quality Protection Act* (FQPA) amendments and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended labels of all end-use products containing pyrazon.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to pyrazon may occur through consumption of food and water, residential exposure, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures, using the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but measures to mitigate risk would be required. The toxicological end-points selected by the USEPA for assessment of risk from occupational exposure are summarized in Appendix II.

Workers can be exposed to pyrazon through mixing, loading or applying the pesticide, and when re-entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

No long-term occupational exposure was anticipated based on the use pattern. In addition, no dermal endpoint of concern for short- and intermediate-term exposures was identified, and therefore no occupational risk assessment was done for this route of exposure.

Twenty-six potential exposure scenarios for short- and intermediate-term inhalation exposure of occupational handlers were identified. Among the scenarios assessed in the RED, the following were considered relevant to the Canadian use pattern:

- mixing/loading of liquids for groundboom application at a rate of up to 8.5 kg a.i./ha
- mixing/loading of wettable granules for groundboom application at a rate of up to 8.1 kg a.i./ha
- application of sprays by groundboom at a rate of up to 8.5 kg a.i./ha.

Handler exposure analyses were performed using surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, assuming baseline personal protective equipment (PPE) of long-sleeved shirt, long pants, and shoes plus socks. Short-term/intermediate inhalation risk was based on maximum pyrazon application rates of 8.5 kg a.i./ha, standard assumptions for area treated per day (32.4 ha/day), medium- to high-end estimates of area treated daily, a NOAEL of 18 mg/kg/day from a rat chronic feeding study, and a target margin of exposure (MOE) of 100.

The USEPA reported acceptable short-term/intermediate inhalation MOEs for these occupational exposure scenarios, ranging from 1500 to 5000. Based on these quantitative assessments, no mitigation measures were required.

The RED adequately addressed potential exposure scenarios associated with the Canadian uses of pyrazon, and conclusions derived from the RED are considered to be applicable to the Canadian situation. Current PPE recommended on Canadian labels include long-sleeved shirt, trousers, rubber boots, hat, goggles or face shield, and gloves (rubber/PVC/neoprene/nitrile). These are considered adequate, and no further mitigation is required.

3.1.1.2 Postapplication Exposure and Risk

The USEPA did not assess occupational postapplication risks to agricultural workers because no dermal endpoint of concern was identified, and inhalation exposure was expected to be negligible. In addition, mechanical harvesting and application well prior to crop maturation would limit the nature of potential postapplication exposure.

The 1992 USEPA Worker Protection Standard (WPS) is intended to decrease the number of injuries from handling pest control products. A restricted-entry interval (REI) is the period of time following a pesticide application during which workers are not allowed to re-enter the treated area. According to the WPS, the length of the REI is determined by the toxicity of the active ingredient. Based on the WPS and on the low acute toxicity of the technical (Toxicity Category III or IV), the USEPA required a REI of 12 hours on pyrazon product labels for all uses. This was considered applicable to the Canadian situation. Therefore the PMRA will require a minimum REI of 12 hours on labels of currently registered Canadian pyrazon products to further protect workers from postapplication exposure. Proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

No residential exposure was expected from commercial uses of pyrazon, and therefore a residential risk assessment was not conducted. In Canada, there are no residential uses registered, and no residential exposure is expected from commercial uses of pyrazon.

3.1.2.2 Exposure from Food and Drinking Water

An acute endpoint of toxicological concern was not identified. On this basis, an acute risk assessment was not conducted.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it was expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation (see Appendix II).

Exposure to pesticides through drinking water can occur as a result of groundwater or surface water contamination. Both acute (one day) and chronic (multiple year) drinking water risks are considered, using either modelling or actual monitoring data, if available, to estimate those risks. Modelling is carried out in tiers of increasing refinement, but is designed to provide high-end estimates of exposure. The risk assessment may be conducted by the "drinking water level of comparison" (DWLOC) approach or assessed probabilistically in DEEM/Lifeline.

A Tier I chronic dietary risk assessment due to risk from food and drinking water was conducted using the Lifeline Model Version 3.0, which incorporates food consumption data from the United States Department of Agriculture (USDA) Continuing Survey of Food Intakes by Individuals (CSFII) from 1994-6 and 1998, using the Dietary Exposure Evaluation Model (DEEM) Version 2.03, resulting in <0.1% of the cPAD for all population subgroups. This assessment was based on a cPAD of 0.18 mg a.i./kg b.w./day, which was calculated from a rat chronic toxicity study (NOAEL of 18 mg a.i./kg b.w./day, uncertainty factor 100×, and FQPA factor of 1×). Assumptions included 100% crop treated, recommended tolerance-level residues, and default processing factors.

Pyrazon was found to be persistent and mobile in the environment and to have the potential to reach surface water via runoff and/or spray drift and to contaminate groundwater via leaching. The USEPA determined that over 99% of dietary exposure to pyrazon was due to drinking water. The maximum estimated drinking water concentration (EDWC) was 655 ppb, based on Tier II surface water modelling using Pesticide Root Zone Model and the Exposure Analysis Modelling System (PRZM/EXAMS) Index Reservoir Model. This estimate was based on broadcast application to sugar beet modelled with a maximum application rate of 8.18 kg a.i./ha. The

USEPA used the DEEM and Lifeline models, with conservative assumptions in their assessments, including 100% crop treatment, reassessed tolerance-level residues and screening-level drinking water concentrations. Water exposure was incorporated directly into the DEEM-FCID (Functional Configuration Identification Database) and Lifeline dietary exposure analyses. The USEPA considered the estimated combined chronic exposure to pyrazon from food and drinking water (25% of cPAD) to be below its level of concern, and no mitigation with respect to dietary risk was required. Based on the potential for pyrazon to leach to groundwater, the USEPA required a statement protective of ground water resources.

The current Canadian registered uses of pyrazon are encompassed by this assessment. The U.S. tolerances encompassed Canadian MRLs (i.e. 0.1 ppm general MRL³), and the application rate used in the drinking water assessment encompassed the Canadian maximum application rate. Therefore, the USEPA assessment is considered to be applicable to the Canadian situation. As required in the USEPA RED, the PMRA will recommend a ground water statement. This proposed label amendment is listed in Appendix III.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to pyrazon (i.e. from food and water). Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures. Short-term and intermediate aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

An acute aggregate exposure and risk assessment was not conducted due to the lack of an endpoint of concern for acute exposure. Nor was a cancer aggregate risk assessment conducted, based on the fact that pyrazon was classified as "not likely to be a carcinogen to humans." There were no residential uses expected to contribute to short-term and intermediate exposures for this chemical, based on its current use patterns. Therefore, short-term and intermediate aggregate assessments were not conducted. In addition, the chronic aggregate risk assessment was based on food and drinking water exposures only. See Section 3.1.2.2 for conclusions.

The USEPA estimated aggregate chronic risk for infants, the most sensitive subpopulation, to be 21% and 25% of the cPAD, using the Lifeline and DEEM-FCID dietary models respectively. These estimates were considered to be below the level of concern.

Overall, the Canadian potential aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of pyrazon in Canada.

³ Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

3.1.3 Cumulative Effects

The USEPA has not determined whether pyrazon has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that pyrazon does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

Pyrazon was found to be persistent and mobile in the environment and to have the potential to reach surface water via runoff and spray drift and to contaminate groundwater via leaching. Therefore, additional groundwater and surface water advisory statements were required by the USEPA. These conclusions were determined to be applicable to the Canadian situation, and groundwater as well as surface water advisory statements should be required. Appendix III lists all label amendments.

To assess the ecological risk of pyrazon to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity end-points and expected environmental concentrations (EECs), and compared the resulting RQs to corresponding levels of concern (LOCs).

Aquatic EEC's were estimated using the Pesticide Root Zone Model and the Exposure Analysis Modelling System (PRZM/EXAMS) and based on the maximum application rate of 8.18 kg a.i./ha in addition to typical application rates of 1.89, 2.89 and 3.90 kg a.i./ha. Acute RQs (<0.001 to <0.0062) for freshwater fish and acute RQs (<0.0007 to <0.0015) for aquatic invertebrates did not exceed the acute risk LOC of 0.5 or the endangered species risk LOC of 0.05 and were not of concern. Acute risk to marine/estuarine fish and invertebrates and chronic risk to both freshwater and marine/estuarine fish and invertebrates were not assessed by the USEPA due to lack of available studies. Aquatic plant RQs fell below the LOC of 1.0 for both macrophytes and algae, with the exception of RQs of 1.167 to 3.200 for algae at application rates of 8.18 and 3.90 kg a.i./ha.

For mammals and birds, EEC's were calculated using the Terrestrial Residue Exposure (T-REX) model and based on typical food consumption parameters by various species following application of 1.89, 2.89, 3.90 or 8.18 kg a.i./ha of pyrazon. Acute diet-based RQ values for birds ranged up to 0.41, and did not exceed the acute avian LOC of 0.5 at any application rate. Chronic risk to birds could not be assessed due to lack of available studies. Acute RQ values for mammals did not exceed the acute risk LOC of 0.5 at any application rate. Diet-based chronic RQs ranged up to 8.77 (based on a rat developmental NOAEL for maternal toxicity of 200 mg/kg diet) and exceeded the chronic LOC of 1.0 for chronic risk to mammals at all application rates. However, the USEPA determined that pyrazon may not pose a significant risk to mammalian fetal development because the RQs were based on the only effect demonstrated in the study

(reduced body weight and food consumption of females in gestation) which did not lead to any developmental impairments of the developing fetuses.

Terrestrial plant EEC's were calculated based on application rates ranging from 1.89 to 8.18 kg a.i./ha, using the TerrPlant model. The LOC of 1.0 was exceeded for all application rates for both terrestrial and semi-aquatic plants with RQ values ranging up to 169.46. It was concluded that these exceedences were likely an overestimation of risk because the model assumed that the entire field was treated by broadcast ground or aerial equipment, whereas the registrant had stated that mainly banded application was used, with only a portion of the field being treated using only ground equipment.

The USEPA did not require mitigation measures with respect to ecological risk at the time of the RED publication because they considered the ecological risk assessments to be a screening-level analysis. Label statements regarding drift, runoff, and leaching, were required by the USEPA because pyrazon was found to be persistent and mobile in many types of soil, and therefore, had the potential to enter surface and ground water. Based on this the PMRA will require groundwater as well as surface water advisory statements. Furthermore, the PMRA will require terrestrial and aquatic buffer zones for pyrazon end-use products to protect aquatic organisms and terrestrial plants from spray drift. Proposed label amendments are listed in Appendix III. Inputs to buffer zone models are described in Appendix IV.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the Federal Government's *Toxic Substances Management Policy* (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The Federal Toxic Substances Management Policy and the Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of pyrazon with the following conclusions:

- Pyrazon is not bioaccumulative; the bioconcentration factor ranges between 2 and 23, which is well below the TSMP threshold value of 5000 $\times$, and the *n*-octanol-water partition coefficient ($\log K_{ow}$) is 1.19, which is below the TSMP Track 1 threshold value of 5.0. Because pyrazon does not meet all Track 1 criteria, it is not a candidate for Track 1 classification.

- Based on a review of the available chemistry, the technical grade active ingredient is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Appendix II of Regulatory Directive DIR99-03.
- Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

4.0 Proposed Regulatory Decision

The PMRA has determined that pyrazon is acceptable for continued registration with the implementation of the proposed risk reduction measures. These measures are required to further protect human health and the environment. Canadian end-use product labels should be amended to include label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The Federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document (Pyrazon, EPA Case No. 2570) is available on the 'Office of Pesticide Programs' website at www.regulations.gov/fdmspublic/component/main under Chemical Status.

List of Abbreviations

a.i.	active ingredient
ARfD	acute reference dose
CAS	Chemical Abstracts Service
cRfD	chronic reference dose
DACO	Data Code
DEEM	Dietary Exposure Evaluation Model
EDWC	estimated drinking water concentration
EEC	estimated environmental concentration
FDA	<i>Food and Drugs Act</i>
FIRST	FQPA Index Reservoir Screening Tool
FQPA	<i>Food Quality Protection Act</i>
g	gram
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol–water partition coefficient
L	litre
LC ₅₀	lethal concentration 50%
LOC	level of concern
mg	milligram
ml	millilitre
MOE	margin of exposure
MRL	maximum residue limit
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
PCPA	<i>Pest Control Products Act</i>
PHED	Pesticide Handlers Exposure Database
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRED	Proposed Re-evaluation Decision
PVC	polyvinyl chloride
RED	Re-registration Eligibility Document
REI	restricted-entry interval
RQ	risk quotient
SCI-GROW	Screening Concentration In Ground Water
TGAI	technical grade active ingredient
TSMP	Toxic Substance Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WPS	Worker Protection Standard

Appendix I Registered Pyrazon Products as of 18 May 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
21115	Technical	BASF Canada Inc.	Chloridazon Technical (Wet)	Solid	65%
15857	Commercial	BASF Canada Inc.	BASF Pyramin FL Liquid Suspension Herbicide	Suspension	27.9%
21116	Commercial	BASF Canada Inc.	Pyramin DF Dry Flowable Herbicide	Dry flowable	65%

Appendix II Toxicological Endpoints Selected by the USEPA for Pyrazon Health Risk Assessments

Exposure Scenario	Dose (mg/kg bw/day)	Study	UF/SF or Target MOE
Dietary chronic	Developmental NOAEL = 18 mg/kg/day cRfD = 0.18 mg/kg bw/day	Chronic feeding study in rat	UF = 100 FQPA SF = 1 × cPAD = 0.18 mg/kg/day
Inhalation Short-/intermediate-/ long-term	Developmental NOAEL = 18 mg/kg bw/day	Chronic feeding study in rat	UF = 100 FQPA SF = 1 × Target MOE = 100
Carcinogenicity	"not likely to be a carcinogen to humans"		

NOAEL = no observed adverse effects level; RfD = reference dose; UF = uncertainty factor; FQPA SF = *Food Quality Protection Act* safety factor; MOE = margin of exposure

^a UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments

Appendix III Label Amendments for Products Containing Pyrazon

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

- I) The following statements should be included in a section entitled "PRECAUTIONS":
- "Do not enter or allow worker entry into treated areas for 12 hours following application."
- II) The following statements should be included in the section entitled "DIRECTIONS FOR USE":
- "Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification."
 - "**DO NOT** apply by air."
 - "**Buffer zones**:

"The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands) and estuarine/marine habitats."

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:			
		Aquatic Habitat of Depths:			Terrestrial habitat
		Less than 1 m	1-3 m	Greater than 3 m	
Field sprayer*	Red table beets / sugar beets	1	0	0	5

*For field sprayer application, buffer zones can be reduced by 70% with the use of shroud spray shields, or 30% with the use of cone spray shields on booms.

"When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture."

III) The following statements should be included in a section entitled "ENVIRONMENTAL HAZARDS":

- "The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow."
- "Toxic to aquatic organisms. To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay)."
- "Avoid application of this product when heavy rain is forecast."
- "TOXIC to aquatic organisms and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."
- "DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

Appendix IV Inputs to Buffer Zone Models for Pyrazon

Ground Use Data (from Canadian labels)				
Crop	Formulation Type	Method of Application	Number of Applications	Maximum Application Rate (g a.i./ha)
Sugar beet/red table beet	Suspension	Field sprayer	1	4400
Sugar beet/red table beet	Dry flowable	Field sprayer	1	4400

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half life for aquatic buffer zones	not applicable	<i>Assumed stable</i>
Most sensitive freshwater species	<i>Selanastrum capricornutum</i>	NOAEC < 0.062 mg a.i./L
Most sensitive estuarine/marine species	not available	not available

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half life for terrestrial buffer zones	Aerobic soil DT ₅₀	190 days - sandy loam 152 days - sandy clay loam
Most sensitive terrestrial plant species EC ₂₅ for seedling emergence	Monocot ryegrass	25 g a.i./ha

